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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/517,956	12/13/2004	Shuji Hinuma	62582(46342)	7274
21874	7590	02/01/2006	EXAMINER	
EDWARDS & ANGELL, LLP			ULM, JOHN D	
P.O. BOX 55874			ART UNIT	
BOSTON, MA 02205			PAPER NUMBER	

1649

DATE MAILED: 02/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/517,956	Applicant(s) HINUMA ET AL.	
	Examiner John D. Ulm	Art Unit 1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-46 is/are pending in the application.
 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-46 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claims 1 to 46 are pending in the instant application.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 1 to 7, 34 and 35, drawn to an **assay** employing "humanin" and a G protein-coupled receptor therefore.

Group II, claims 8, 9, 11 to 14, 36, 37 and 45, only in so far as they relate to an **agonistic compound** of unspecified constitution.

Group III, claims 8, 10, 11, 37 and 45, only in so far as they relate to an **antagonistic compound** of unspecified constitution.

Groups IV to VII, claims 15 to 17, 36 and 37, only in so far as they relate to a receptor protein comprising one of the four different amino acid sequences recited therein, and methods of use. Group IV, for example, consists of claims 15 to 17, 36 and 37 only in so far as they relate to SEQ ID NO:1. Group VII consists of claims 15 to 17, 36 and 37 only in so far as they relate to SEQ ID NO:14.

Group VIII to XI, claims 18 to 22, 25, 26, 30, 31, 36 and 37, only in so far as they relate to a polynucleotide encoding one of the four amino acid sequences recited therein, and methods of use.

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Group XII to XV, claims 23 and 24, only in so far as they relate to an antibody that binds to a receptor protein comprising one of the four different amino acid sequences recited therein.

Group XVI, claims 27 to 29, 32 and 33, drawn to a compound of unspecified constitution that increases the expression level of a protein.

Group XVII, claims 38 to 44 and 46, drawn to "Humanin" and a method of use.

The inventions listed as Groups I to XVII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The assay of invention I is distinguished from the art by the **combination** of Humanin with a receptor therefore because the text on pages 2 to 4 of the instant application concedes Humanin and the Humanin receptors FPRL-1 and FPRL-2 to the prior art. This combination is not present in any of inventions I to XVII. The compounds of invention II to XVII do not reflect a single inventive concept because they lack a corresponding special technical feature that distinguishes them as a group from the prior art. The four different receptor proteins that define inventions IV to VII, for example, are related to one another because they are Humanin receptors that are members of the G protein-coupled receptor family. They are not distinguished as a group from the prior art because the instant application has admitted that the G protein-coupled Humanin receptors FPRL-1 and FPRL-2 were known in the art before the making of the instant invention.

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This application contains claims directed to more than one disclosed species of receptor protein, as recited in claim 1, for example, and more than one disclosed species of Humanin, as recited in claim 39. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1. The different receptors recited in the claims do not reflect a common inventive concept for those reasons given above. The species of Humanin do not reflect a common inventive concept because the specification has conceded Humanin to the prior art and all proteins produced in living systems are initially synthesized with a formyl-methionine at the amino terminus.

Applicant is required, in reply to this action, to elect a single species of receptor protein and Humanin to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John D. Ulm whose telephone number is (571) 272-0880. The examiner can normally be reached on 9:00AM to 5:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on (571) 272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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A handwritten signature in black ink, appearing to read 'J. ULM', with a long horizontal stroke extending to the right.

**JOHN ULM
PRIMARY EXAMINER
GROUP 1800**